

Remarks:

Applicants have read and considered the Office Action dated June 23, 2010 and the references cited therein. Claim 1 has been amended. Claims 1-12 are currently pending. Reconsideration is hereby requested.

In the Action, the specification was objected to because it introduces new matter. The Office Action contends that “wherein said member is removable to expose the at least one channel” introduces new matter as it is not supported by the original specification. Although Applicants assert that the channels 32 are clearly exposed when the member 31 is removed, claim 1 has been amended to recite that portions of the at least one channel that are formed by the nozzle element are exposed when the member is removed. Applicants assert that can clearly be seen as shown in Figures 1, 4 and 5. Applicants assert that the objection to the specification has been overcome and requests that it be withdrawn.

Claims 1-9 were rejected 35 U.S.C. § 112, second paragraph, as being indefinite. The Action states that “wherein said member is removable to expose the at least one channel” recited in claim 1 renders the claims indefinite as it is unclear how the member can expose the channel when the channel is defined in part by the member. Although Applicants assert that the channels are only partially defined by the member and therefore that the channels would be exposed if the member were removed, the language at issue has been amended. The claim now recites that portions of the at least one channel formed by the nozzle element are exposed upon removal of the cover. Applicants assert that this can clearly be seen in Figures 1, 4 and 5 and is supported by the specification as originally filed and provides for improved cleaning. Applicants assert that the rejection under 35 U.S.C. § 112, second paragraph, has been overcome and requests that it be withdrawn.

Claims 1, 2, 5, 10 and 12 were rejected under 35 U.S.C. § 102(b) as being anticipated by Pitcher or in the alternative, as being rejected under 35 U.S.C. § 103(a) as being obvious over Pitcher. Moreover, claims 3, 4, 6-9 and 11 were rejected under 35 U.S.C. § 103(a) as being obvious over Pitcher. Applicants respectfully traverse the rejections.

Lester discloses an inhalation therapy device with a nozzle element labeled as air nozzle 14 on which a bulbous-type connector 31 is attached for connecting an air pressure hose. The spray nozzle 15 of Lester is permanently attached to an outer casing of the device, referred to as a bowl. Lester describes a spray nozzle 15 at column 3, lines 10-14 as bowls "Extending upward on the inside of the bowl 11 from its lower end is a slightly tapered-tubular spray nozzle 15, preferably formed integrally with the bowl 11."

Moreover, the inner nozzle 14 is also permanently attached to the outer casing as recited at column 3, lines 61-70. "A shoulder 32 of the nozzle 14 is preferably proportioned to seat upon the lower end of the bowl 11, for positioning the nozzle 14 and firmly supporting it in its correct relationship to the spray nozzle 15. As depicted in the drawings, the shoulder 32 is relatively wide and, consequently, gives sturdy, firm support. This results in a very strong union of parts, in fact, one which is practically indestructible, and so substantially eliminates the danger of nozzle fracture commonly encountered with other nebulizing devices."

Finally, Lester again describes the assembly of the system with the nozzles 14 and 15 being permanently configured as part of the Nebulizer at column 5, lines 5-12. "Assembly-wise, since the spray nozzle 15 is molded integrally with the bowl 11, its position is established at the outset. When the air nozzle 14 is inserted into the spray nozzle 15, the broad mounting shoulder 32 securely and properly positions the nozzle 14. The use of a small amount of adhesive or other plastic joining material quickly and securely unites all the parts into one durable unit."

From the description of Lester, it is clear that a spray nozzle and air nozzle are not detachable and movable to expose channels between the spray nozzle and the air nozzle.

Claim 1 has now been amended and recites the aerosol generator comprises a nozzle element and at least one channel extending between the nozzle element and a member. Claim 1 further recites that the member is removable to expose portions of the at least one channel. As discussed above, the spray nozzle and air nozzle are permanently affixed as part of the nebulizer in Lester. Therefore, Lester neither teaches nor suggests any sort of removable member that allows for cleaning of the channels. The present invention provides for easily cleaning the nozzle element without causing any damage to sensitive parts that are critical to create the proper aerosol delivery. With prior art devices, the geometries important to creating an aerosol may be adversely affected through cleaning by patients who are unaware of the consequences of their actions. The removable member of the present invention provides for easily and thoroughly cleaning the nozzle element and the ability to remove particles tightly adhering to the exposed surfaces by use of cleaning brushes or cloths. Applicants assert that this is not possible or even suggested by Lester or any other prior art or combination thereof. It should be noted that Lester does not provide for cleaning of any of the inner nozzle as all parts are affixed to one another. Therefore, the Lester device is likely disposed of rather than being cleaned as is possible with the devices of the present application and as recited in claim 1.

Applicants assert that claim 1 recites nonobvious differences that are not possible with Lester or obvious in view of Lester. Applicants therefore assert that claim 1 patentably distinguishes over Lester. Moreover, the claims depending there from also patentably distinguish over Lester for at least the same reasons as well as others. Applicants request that the rejections over Lester be withdrawn.

Claim 1 has been amended to recite that the member is removable so that when removed, portions of the channels that are formed by that element are exposed and may be easily cleaned.

This removal of the cover type member 31 allows for exposing the portions of the channels 32 defined by the nozzle element 5 and facilitates easy and direct cleaning of those exposed surfaces. The Office Action alleges that Pitcher discloses channels, referred to as passages, between a sleeve and gas duct in Pitcher, there is no teaching or suggesting that the alleged "channels" could be exposed in any way. Moreover, Pitcher actually teaches away from the present invention as Pitcher recites at column 2, starting at line 57: "However, mounted on top of gas duct 6, and integral therewith is first chamber 9, which opens toward housing in portion 2 but is separated...". When viewing the figures for this passage, it can readily be understood that the channels cannot be exposed in any manner and that removal of parts would not lead to exposing any portions of the channels. Since the first chamber 9, the gas duct 6 are mounted integrally with each other, it is not possible to access the portion of the channels indicated by reference numeral 12, which surrounds the first chamber and also forms the chamber. Moreover, it is also impossible to expose channels 5 and the jet head 3. Channels 5 are formed as a through hole within the integrally formed jet head 3 so that opening and exposing of these channels is not possible.

Upon closer review and analysis of the cited prior art, it can be seen that the Pitcher reference neither teaches nor suggests any sort of device that allows for removal of an element or member that would allow for exposing portions of channels formed by the remaining elements as is possible with the present invention. Pitcher does not have an objective to provide for easy cleaning of any sort of inhalation device and does not provide for exposing any portions of the alleged channels in question to provide exposure and access for easy cleaning. The present invention provides an easily removable member that allows for portions of the channels to be exposed on the nozzle element and therefore easily cleaned. Applicants assert that the problems associated with cleaning and maintaining the inhalation device and hygienic condition are not possible with Pitcher or any other prior art or combination thereof. Applicants assert that claim 1

patentably distinguishes over Pitcher or any other prior art. Applicants therefore request that the rejection of claim 1 under 35 U.S.C. § 102(b) and/or 35 U.S.C. § 103(a) be withdrawn.

Moreover, claim 10 is believed to patentably distinguish over the Pitcher reference as there is no teaching or suggestion of Pitcher having parts with a first resilience and a second part having a different resilience. The Office Action contends that even if Pitcher does not teach differences in resilience, it would have been obvious to one of ordinary skill in the art at the time the invention was made, as the first part of a more resilient material setting would be easily cleanable without a danger of breakage. However, as discussed above, the portions of the nozzle element in question cannot be exposed for easy cleaning and therefore the motivation to provide different resiliencies for being easily cleanable would not be possible with Pitcher, as the channels and passages in question remain covered and are not easily accessed. As there is no motivation to modify the Pitcher reference, Applicants assert that claim 10 patentably distinguishes over Pitcher. Applicants therefore request that the rejection under 35 U.S.C. § 102(b) and/or under 35 U.S.C. § 103(a) over Pitcher be withdrawn.

Applicants further assert that the claims depending from claim 1 and claim 10 also patentably distinguish over the prior art including the Pitcher reference, and any other prior art or combination thereof. Applicants therefore request that the rejections of the dependent claims be withdrawn.

A speedy and favorable action in the form of a Notice of Allowance is hereby solicited. If the Examiner feels that a telephone interview may be helpful in this matter, please contact Applicant's representative at (612) 336-4728.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725.



Respectfully submitted,

MERCHANT & GOULD P.C.

Dated: _____

10/25/10

By: _____

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GAS/km